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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MOSHER, MARY

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 09/04/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/921,397

Applicant(s)

LEGRAIN ET AL.

Examiner

Mary E. Mosher, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 2/19/2003, 6/11/2003, 2/26/2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) 7-11, 22, 23, 25, 27-61 and 63-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-6, 12-21, 24, 26 and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restrictions

Applicant's election with traverse of claims 1-6, 12-21, 24, 26, and 62, SEQ ID NO: 58 in Paper No. 13 and 11 is acknowledged. The traversal is on the ground(s) that claims 27-30, 44-50, and 64, which recite nucleic acids, would not be burdensome to examine together with these nucleic acid claims. This is not found persuasive for several reasons. First, claims 27-30 and 63 are drawn to alternative different methods of use of the claimed nucleic acid; the nucleic acids can be used in other materially different process such as the process of making the encoded polypeptides, or the protein/nucleic acid binding process of claims 52 and 53. Claims 44-50 are drawn to a nucleic acid which encodes "marker compound according to claim 42." This "compound" comprises a SID polypeptide covalently bound to a first ligand and a second ligand which binds to the first ligand. The ligands are not specified as proteins and are not specified as fused to the SID polypeptide. Therefore, the "marker compound of claim 42" is actually a complex comprising three different molecules, where one molecule is a protein, two of the three molecules are covalently associated and one of the three molecules may be noncovalently associated. Claims 44-50 are directed to a nucleic acid which somehow encodes this tripartite complex.

On reading the claims, it is very unclear how one could make one nucleic acid which specifies three different products AND dictates that all the products bind to each other. Therefore the patentability of the nucleic acid of claims 44-50 does not lie solely in the structure of the SID coding sequence; patentability could lie in somehow encoding a non-protein ligand, or in whatever elements of the nucleic acid ensure the covalent

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binding of the SID polypeptide with the first ligand and the (noncovalent?) binding of the SID-ligand with the second ligand. Claim 64 is drawn to still another method of use of the nucleic acid.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7-11, 22, 23, 25, 27-61, 63-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group and/or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11 and 13. Claims 1-6, 12-21, 24, 26, 62 have been examined to the extent that they read upon SEQ ID NO: 58 or a sequence encoding SEQ ID NO: 20.

Claim Rejections - 35 USC § 112

Claims 1-6, 12-21, 24, 26, 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for several reasons. First, the claim recites "a polypeptide consisting essentially of the amino acid sequences of SEQ ID Nos; 1 to 38 or a sequence complementary thereto." It is not clear how something can be complementary to an amino acid sequence. The specification does not define what applicant means by "consisting essentially of" an amino acid sequence.

Conventionally, the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549,

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551-52, 190 USPQ 461, 463 (CCPA 1976). However, this cannot be what applicant means, because dependent claim 2 permits sequences that are different from SEQ 1-38, and dependent claim 5 permits sequences that contain less than the material of SEQ ID 1-38. Since applicant does not explicitly define "consisting essentially of," and uses the phrase in a manner inconsistent with its conventional meaning, it is completely unclear what "consisting essentially of" means in these claims.

Second, it is not clear how the nucleic acid sequences relate to the amino acid sequences. Specification page 12 indicates that nucleic acid sequences 39-76 encode polypeptides 1-38. Therefore, elected nucleotide sequence 58 should encode polypeptide 20. But Table 1 conflicts with this, stating that nucleotide sequence 58 encodes polypeptide 21. Consulting the sequence listing filed with the application further confuses the situation, since the translation product of sequence 58 does not match either polypeptide 20 or 21. Therefore, it is very unclear what polypeptide is encoded by the claimed nucleic acid, and very unclear what degenerate coding sequences are intended in claim 1, what fragmentary sequences are intended in claim 5, and what variants are intended in claims 2, 4, and 6.

These problems all affect dependent claims 12-21 and 64. In the interest of compact prosecution, these claims have been treated as if they were drawn to a nucleic acid encoding a sequence comprising SEQ ID NO: 20 or to a nucleic acid comprising SEQ ID NO: 58.

In addition, claims 18 and 19 are confusing, are these claims meant to be a list of alternative vectors or are they meant to be a composition containing all the recited

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vectors? In addition, are the claims directed to the recited plasmids, or to plasmids with inserted DNA? For example, if the claimed plasmid "is pT25", then it excludes any inserted DNA, since pT25 as defined in Figure 6 does not include an insert.

Claim 24 is confusing, because the claim preamble states "a set of two polypeptides" but the body of the claim recites nucleic acid sequences. In addition, a "set" is not one of the statutory categories of "process, machine, manufacture, or composition of matter." Is the intention to claim a composition consisting essentially of the two recited compounds, or a manufactured kit comprising the two compounds in one or more containers? In claim 26, how do the two nucleic acids of claim 24 form a complex?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is apparent that the plasmids recited in claims 17-19 are required to practice the claimed invention, since they are specifically recited in these claims. As required elements the plasmids must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement

requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the plasmids recited in these claims. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining these plasmids, and they do not appear to be readily available material. The application provides figures which disclose some of the characteristics of the plasmids, but does not provide enough information to re-create the specific plasmids named in the claims. Deposit of the plasmids named in the claims would satisfy the enablement requirements of 35 U.S.C. 112. See 37 CFR 1.801- 1.809.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

- (a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;
- (b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;

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(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

Claims 1-6, 12-21, 24, 26, and 62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims are drawn to a nucleic acid, where the only use taught for the nucleic acid involves expression of the encoded product. Claim 62 is drawn to a pharmaceutical composition comprising a nucleic acid. The elected species of nucleic acid (SEQ ID NO:58) is a fragment of the NS5B coding region, corresponding to NS5B amino acids 495-539. Table 1, on page 78, indicates that this peptide binds to polypeptide of 225 amino acids which spans the NS4B/NS5A cleavage site. The specification asserts that the claimed peptide can be used "for detection purposes," but fails to teach why detection of the NS4B/NS5A peptide would be of

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interest. The specification also asserts that the claimed peptide can be used "for interfering with a naturally occurring interaction between a first protein and a second protein within the cell of an organism," but fails to teach that an interaction actually occurs between the natural proteins containing these sequences, and fails to teach what biological effect (if any) results when this putative interaction is interfered with. In addition, the specification fails to teach how to deliver the claimed pharmaceutical nucleic acid to infected cells and achieve expression in a manner effective to treat or prevent HCV infection. Gene therapy treatments of virus infection were not recognized as successful in the art, at the time the invention was made. Considering the limited teachings in the specification, the absence of any working example showing a practical use for the claimed peptide, and the state of the art, it is concluded that undue experimentation would be required to use the claimed polypeptide in the manner suggested in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 12-16, 20, 21, 24, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Yanagi et al (PNAS 94:8738-8743, 1997). Yanagi teaches a nucleic acid that comprises SEQ ID NO:58 and SEQ ID NO: 132. Since applicant's

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meaning of "consisting essentially of" is undefined and unconventional, the claims are given the broadest reasonable interpretation of "comprising" the recited sequence.

Conclusion

A nucleic acid consisting of a sequence encoding SEQ ID NO:20, and a nucleic acid consisting of SEQ ID NO:58, would be free of the art, because the prior art does not teach or suggest an NS5B fragment with these precise endpoints.

Lesburg et al (Nature Structure Biology 6:937-943, 1999) is cited as of interest in disclosing that the claimed peptide (corresponding to residues 495-539) is found mainly in the "thumb" subdomain of the NS5B polymerase protein (residues 371-528). Lesburg teaches that this region includes an alpha helix containing six arginines important to polymerase activity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 703-308-2926. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Mary Mosher
MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1600 /600
